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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1795	
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07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,295	YAMAOKA ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/13/2009 (response to restriction)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *25-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the inv eto of Group I, claims 1-24, in the reply filed on April 13, 2009 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 1-3, 8-12, and 19-23, are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. US 6,436,255 B2 ("Yamamoto").

Addressing claim 1, Yamamoto discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (12) for moving a sample containing blood cells (col. 01:29-37 and col. 09:09-13), an introduction port (10) for introducing the sample into the flow path (Figures 4-7), a reagent portion arranged in the flow path (col. 08:57 – col. 09:08), and an electron detection medium (4,5) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (col. 08:52-56 and col. 09:09-20); wherein the reagent portion contains an electron mediator for supplying an electron taken from the analysis target component in the sample to the electron detection medium (col. 08:57-59), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 4 and col. 08:66 – col. 09:08).

Addressing claim 2, the additional limitation of this claim may be inferred from Figures 1 and 3-7.

Addressing claim 3, for the additional limitation of this claim see col. 08:05-38.

Addressing claim 8, for the additional limitation of this claim note the electrodes (2,3).

Addressing claim 9, for the additional limitation of this claim see col. 08:31-44.

Addressing claim 10, for the additional limitation of this claim see col. 01:20-29.

Addressing claim 11, for the additional limitation of this claim see col. 03:55-61 and col. 07:55 – col. 08:04.

Addressing claim 12, for the additional limitation of this claim note the locate of oxidoreductase layer 18 relative to the mediator carrier 13 and the electrodes (2,3).

Addressing claim 19, for the additional limitation of this claim see col. 08:31-38 and col. 09:20-25.

Addressing claims 20 and 23, for the additional limitations of these claims see col. 04:40-44.

4. Claims 1-3, 8, 9, 20, 21, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakaminami et al. US 6,740,215 B1 ("Nakaminami").

Addressing claim 1, Nakaminami discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (10) for moving a sample containing blood cells (this is an intended use of which the analytical instrument is capable as the instrument is intended for "… simple quantification of body fluid components by ordinary people …" – col. 01:10-14), an introduction port (right end of channel 10 in Figures 1 and 2) for introducing the sample into the flow path (col. 05:08-12)), a reagent portion arranged in the flow path (col. 05:40-45 and col. 07:14-24), and an electron detection medium (4,5) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (col. 06:11-30); wherein the reagent portion contains an electron mediator for supplying an electron taken from the analysis target component in the sample to the electron detection medium (col. 02:55-64), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 2 and col. 05:40-49 and col. 07:14-23).

Addressing claim 2, for the additional limitation of this claim see Figure 2. note the sample inlet at the right end of the analytical instrument, to its immediate left the reagent portion, and to the left of the reagent portion the electron detection medium (electrodes 2 and 3).

Addressing claim 3, for the additional limitation of this claim see col. 05:27-34, which discloses sample dissolving the reagent system and col. 05:40-45 and col. 07:14-20, which discloses locating the reagent separate from the electrode system

Addressing claim 8, for the additional limitation of this claim note the electrodes (2,3).

Addressing claim 9, for the additional limitation of this claim see col. 06:11-17.

Addressing claims 20, 21, and 23, for the additional limitations of these claims see col. 03:19-29.

Addressing claim 24, for the additional limitation of this claim see col. 05:27-34.

5. Claims 1, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Harding et al. US 6,261,519 B1 ("Harding").

Addressing claim 1, Harding discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (16) for moving a sample containing blood cells (abstract and col. 07:56-57), an introduction port (12) for introducing the sample into the flow path (col. 07:56-57), a

reagent portion arranged in the flow path (col. 07:50–53), and an electron detection medium for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (col. 07:56-64); wherein the reagent portion contains an electron mediator ($K_3 Fe(CN)_6$) for supplying an electron taken from the analysis target component in the sample to the electron detection medium (col. 07:56-64), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 1 and col. 07:50–53).

Addressing claim 6, for the additional limitation of this claim see col. 04:16-20 and col. 04:45-46, which teach that the analytical instrument is suitable for a "Chromgenic Factor XIIa Assay" and "Colorimetric Assay for Nitric Oxide".

Addressing claim 7, for the additional limitation of this claim see col. 05:37-42, which discloses that the reagent may be located therein and page 15, line 25 - page 16, line 07, which discloses that the reagent ,may be located in a gel.

6. Claims 1-3, 8, 10-12, 20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson GB 2254436 A ("Wilson").

Addressing claim 1, Wilson discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (14 + 17) for moving a sample containing blood cells (abstract; page 01, lines 07-09; page 05, lines 30-31), an introduction port (defined by left end of element 15 in Figure 1) for introducing the sample into the flow path (page 01, lines 25-30), a reagent portion (16) arranged in the flow path (Figure 1), and an electron detection medium (12) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (page 04, lines 11-26); wherein the reagent portion contains an electron mediator (e.g., NADH; 1,1'-dimethyl-ferrocene; potassium ferricyanide – Figure 3 and page 04, line 27 – page 05, line 13) for supplying an electron taken from the analysis target component in the sample to the electron detection medium (Figure 3), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 1).

Addressing claim 2, for the additional limitation of this claim see Figure 1.

Addressing claims 3 and 19, for the additional limitation of this claim see page 06, lines 09-19.

Addressing claim 8, for the additional limitation of this claim note that electrodes are inherently conductive. See Figure 2.

Addressing claim 10, for the additional limitation of this claim see Figure 3 and page 04, line 27 – page 05, line 13.

Addressing claims 11 and 12, for the additional limitations of these claims see page 07, lines 16-26; page 03, lines 32-33; and Figure 1, which disclose providing several reagent bands.

Addressing claims 20 and 23, for the additional limitations of these claims see page 04, lines 27-32.

Addressing claim 24, for the additional limitation of this claim see page 02, lines 08-21.

Claim Rejections - 35 USC § 103

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson GB 2254436 A ("Wilson").

Wilson discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (14 + 17) for

moving a sample containing blood cells (abstract; page 01, lines 07-09; page 05, lines 30-31), an introduction port (defined by left end of element 15 in Figure 1) for introducing the sample into the flow path (page 01, lines 25-30), a reagent portion (16) arranged in the flow path (Figure 1), and an electron detection medium (12) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (page 04, lines 11-26); wherein the reagent portion contains an electron mediator (e.g., NADH; 1,1'-dimethyl-ferrocene; potassium ferricyanide – Figure 3 and page 04, line 27 – page 05, line 13) for supplying an electron taken from the analysis target component in the sample to the electron detection medium (Figure 3), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 1).

Wilson does not mention having the center-to-center distance between the reagent portion and the electron detection medium set as claimed. As a first matter, the additional limitation of claim 4 appears to be only an intended use that does not further structurally limit the invention because when the electron transfer from the maximum amount of analysis target compound component is substantially completed will depend on a number of operational factors, such as what the sample is , what the mediator is, the presence of any ingredients in the reagent or sample which may affect reaction kinetics, and the viscosity or flow rate of the reagent/ sample mixture. In any event, it would have been obvious to configure the analytical instrument as specified by claim 4 because it is clearly desirable to have the electron transfer from the maximum amount of analysis target compound component be substantially completed before the

electron mediator becomes able to supply electrons to the electron detection medium as this will improve the accuracy of the measurement. As stated by Wilson, "In use, a sample for analysis, and liquid to mobilize the reagent or regents, are applied to the capillary body and *the resultant reaction influences the electrode assemble in a manner dependent on the sample to provide a related quantitative output from the instrument*"[emphasis added]. See page 01:25-32.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson GB 2254436 A ("Wilson").

Wilson discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (14 + 17) for moving a sample containing blood cells (abstract; page 01, lines 07-09; page 05, lines 30-31), an introduction port (defined by left end of element 15 in Figure 1) for introducing the sample into the flow path (page 01, lines 25-30), a reagent portion (16) arranged in the flow path (Figure 1), and an electron detection medium (12) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (page 04, lines 11-26); wherein the reagent portion contains an electron mediator (e.g., NADH; 1,1'-dimethyl-ferrocene; potassium ferricyanide – Figure 3 and page 04, line 27 – page 05, line 13)

for supplying an electron taken from the analysis target component in the sample to the electron detection medium (Figure 3), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 1).

Wilson does not mention having the content of the electron mediator in the reagent portion so set that, when the sample contains the analysis target component in maximum amount of a predetermined detection range, the electron mediator can receive all the electrons taken from the maximum amount of analysis target component. As a first matter, the additional limitation of claim 4 appears to be only an intended use that does not further structurally limit the invention because the maximum amount of predetermined range is not specified. In any event, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide sufficient electron mediator for the expected amount or concentration of target analyte in the sample. One with ordinary skill in the art would know the usual range of target analyte, for example, glucose, in the sample source, such as blood. As stated by Wilson, "In use, a sample for analysis, and liquid to mobilize the reagent or regents, are applied to the capillary body and *the resultant reaction influences the electrode assemble in a manner dependent on the sample to provide a related quantitative output from the instrument*" [emphasis added]. See page 01:25-32.

11. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson GB 2254436 A ("Wilson").

Wilson discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (14 + 17) for moving a sample containing blood cells (abstract; page 01, lines 07-09; page 05, lines 30-31), an introduction port (defined by left end of element 15 in Figure 1) for introducing the sample into the flow path (page 01, lines 25-30), a reagent portion (16) arranged in the flow path (Figure 1), and an electron detection medium (12) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (page 04, lines 11-26); wherein the reagent portion contains an electron mediator (e.g., NADH; 1,1'-dimethyl-ferrocene; potassium ferricyanide – Figure 3 and page 04, line 27 – page 05, line 13) for supplying an electron taken from the analysis target component in the sample to the electron detection medium (Figure 3), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 1).

Wilson also discloses providing multiple reagent bands downstream of the electron detection medium in the flow path. These reagent bands comprise enzyme and mediator as desired. See page 07, lines 16-26; Figure 1; and page 03, lines 32-33.

Claims 13-18 require the reagent portion to have a certain length, thickness, or area relative to some other aspect of the analytical instrument. Barring a contrary showing, such as unexpected results, these dimensional requirements on the reagent

portion are just changes in size/ proportion or shape having no consequence on the operation of the analytical deice. See MPEP 2144.04. One with ordinary skill in the art would not expect the thickness or length of a reagent paste to affect the chemistry of its reaction with the sample, especially when the sample will dissolve the reagent. In the *alternative,* one with ordinary skill in the art at the time of the invention would so dimension and locate the reagent portions along so that they would optimally contact and react with the sample.

12. Claims 21 and 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson GB 2254436 A ("Wilson") in view of Nagakawa et al. US 7,390,391 B2 ("Nagakawa").

Wilson discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (14 + 17) for moving a sample containing blood cells (abstract; page 01, lines 07-09; page 05, lines 30-31), an introduction port (defined by left end of element 15 in Figure 1) for introducing the sample into the flow path (page 01, lines 25-30), a reagent portion (16) arranged in the flow path (Figure 1), and an electron detection medium (12) for obtaining information necessary for analyzing an analysis target component contained

in the sample in relation with an amount of electrons transferred (page 04, lines 11-26); wherein the reagent portion contains an electron mediator (e.g., NADH; 1,1'-dimethyl-ferrocene; potassium ferricyanide – Figure 3 and page 04, line 27 – page 05, line 13) for supplying an electron taken from the analysis target component in the sample to the electron detection medium (Figure 3), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 1).

Although Wilson discloses using glucose dehdyrogenase, Wilson does not mention specifically using PQQGDH, αGDH or CyGDH as oxidoreductase, or a Ru complex as an electron mediator.

Nagakawa discloses an electrochemical analytical instrument comprising an oxidoreductase, such as PQQGDH, αGDH or CyGDH and a Ru complex as electron mediator. See the abstract and col. 03:44 – col. 04:56. In light of Nagakawa using PQQGDH, αGDH or CyGDH as oxidoreductase, or a Ru complex as an electron mediator in the analytical instrument of Wilson is just optimizing the reagent for the target analytes.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaminami et al. US 6,740,215 B1 ("Nakaminami").

Nakaminami discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (10) for moving a sample containing blood cells (this is an intended use of which the analytical instrument is capable as the instrument is intended for "… simple quantification of body fluid components by ordinary people …" – col. 01:10-14), an introduction port (right end of channel 10 in Figures 1 and 2) for introducing the sample into the flow path (col. 05:08-12)), a reagent portion arranged in the flow path (col. 05:40-45 and col. 07:14-24), and an electron detection medium (4,5) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (col. 06:11-30); wherein the reagent portion contains an electron mediator for supplying an electron taken from the analysis target component in the sample to the electron detection medium (col. 02:55-64), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 2 and col. 05:40-49 and col. 07:14-23).

Nakaminami also discloses having the reagent portion in a solid state and that it dissolves when the sample is supplied to the flow path. see col. 05:27-34, which discloses sample dissolving the reagent system and col. 05:40-45 and col. 07:14-20, which discloses locating the reagent separate from the electrode system

As for the additional limitation of claim 5, this appears to be only requiring an adequate amount of reagent to completely react with the sample (more especially the

target analyte). One with ordinary skill in the art at the time of the invention would surely determine before-hand the expected range of sample (target analyte) and provide sufficient reagent as the response current is directly proportional to the amount of target analyte in the sample (col. 06:25-28). Too little reagent will result in inaccurate measurement.

14. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakaminami et al. US 6,740,215 B1 ("Nakaminami") in view of Nagakawa et al. US 7,390,391 B2 ("Nagakawa").

Nakaminami discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument comprising a flow path (10) for moving a sample containing blood cells (this is an intended use of which the analytical instrument is capable as the instrument is intended for "… simple quantification of body fluid components by ordinary people …" – col. 01:10-14), an introduction port (right end of channel 10 in Figures 1 and 2) for introducing the sample into the flow path (col. 05:08-12)), a reagent portion arranged in the flow path (col. 05:40-45 and col. 07:14-24), and an electron detection medium (4,5) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (col. 06:11-30); wherein the reagent portion contains an

electron mediator for supplying an electron taken from the analysis target component in the sample to the electron detection medium (col. 02:55-64), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 2 and col. 05:40-49 and col. 07:14-23).

Although Nakaminami discloses a variety of possible enzymes, including PQQGDH, and electron mediators, Nakaminami does not mention using a Ru complex as electron mediator.

Nagakawa discloses an electrochemical analytical instrument comprising an oxidoreductase, such as PQQGDH, αGDH or CyGDH and a Ru complex as electron mediator. See the abstract and col. 03:44 – col. 04:56. In light of Nagakawa using αGDH or CyGDH as oxidoreductase, or a Ru complex as an electron mediator in the analytical instrument of Nakaminami is just optimizing the reagent for the target analytes.

15. Claims 4, 5, 13-18, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. US 6,436,255 B2 ("Yamamoto").

Addressing claim 4, Yamamoto discloses an analytical instrument having improved arrangement of reagent portion (abstract), the analytical instrument

comprising a flow path (12) for moving a sample containing blood cells (col. 01:29-37 and col. 09:09-13), an introduction port (10) for introducing the sample into the flow path (Figures 4-7), a reagent portion arranged in the flow path (col. 08:57 – col. 09:08), and an electron detection medium (4,5) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (col. 08:52-56 and col. 09:09-20); wherein the reagent portion contains an electron mediator for supplying an electron taken from the analysis target component in the sample to the electron detection medium (col. 08:57-59), and wherein at least part of the reagent portion is positioned adjacent to the introduction port (Figure 4 and col. 08:66 – col. 09:08).

Yamamoto also discloses having the reagent portion be in a solid state and dissolving when the sample is supplied to he flow path. See col. 08:05-38.

Yamamoto does not mention having the center-to-center distance between the reagent portion and the electron detection medium set as claimed. As a first matter, the additional limitation of claim 4 appears to be only an intended use that does not further structurally limit the invention because when the electron transfer from the maximum amount of analysis target compound component is substantially completed will depend on a number of operational factors, such as what the sample is, what the mediator is, the presence of any ingredients in the reagent or sample which may affect reaction kinetics, and the viscosity or flow rate of the reagent/ sample mixture. It should also be noted that the reagent portion and electron detection medium in Yamamoto are physically separated, which although the distance is not specified, would not be

expected to be very different in distance than disclosed by Applicant as the dimensions of the channel is on the order of millimeters. See col. 06:39-44; col. 07:64-65; and Applicant's Figures 15A-C. Moreover, it would have been obvious to configure the analytical instrument as specified by claim 4 because it is clearly desirable to have the electron transfer from the maximum amount of analysis target compound component be substantially completed before the electron mediator becomes able to supply electrons to the electron detection medium as this will improve the accuracy of the measurement. In other words, incomplete reactions will result in inaccurate measurements.

Addressing claim 5, Yamamoto also discloses having the reagent portion in a solid state and that it dissolves when the sample is supplied to the flow path. See col. 08:05-38.

As for the additional limitation of claim 5, this appears to be only requiring an adequate amount of reagent to completely react with the sample (more especially the target analyte). One with ordinary skill in the art at the time of the invention would surely determine before-hand the expected range of sample (target analyte) and provide sufficient reagent as the response current is directly proportional to the amount of target analyte in the sample (col. 06:25-28). Too little reagent will result in inaccurate measurement.

Addressing claims 13-18, Yamamoto also discloses an analytical instrument as set forth in claim 12. See the rejection of claim 12 under 35 U.S.C. 102(b) above.

Claims 13-18 require the reagent portion to have a certain length, thickness, or area relative to some other aspect of the analytical instrument. Barring a contrary showing, such as unexpected results, these dimensional requirements on the reagent portion are just changes in size/ proportion or shape having no consequence on the operation of the analytical deice. See MPEP 2144.04. One with ordinary skill in the art would not expect the thickness or length of a reagent paste or layer to affect the chemistry of its reaction with the sample, especially when the sample will dissolve the reagent. In the *alternative,* one with ordinary skill in the art at the time of the invention would so dimension and locate the reagent portions along so that they would optimally contact and react with the sample.

16. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. US 6,436,255 B2 ("Yamamoto") in view of Charlton et al. uS 5,798,031 ("Charlton").

Addressing claim 24, Yamamoto also discloses an analytical instrument as set forth in claim 1. See the rejection of claim 1 under 35 U.S.C. 102(b) above. Although not stated as such the flow path is dimensioned so that it would generate a capillary force. See col. 06:39-44 in Yamamot and col. 05:67 – col. 06:04 in Charlton.

17. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. US 6,436,255 B2 (“Yamamoto”) in view of Nagakawa et al. US 7,390,391 B2 (“Nagakawa").

Yamamoto also discloses an analytical instrument as set forth in claim 1. See the rejection of claim 1 under 35 U.S.C. 102(b) above.

Although Nakaminami discloses a variety of possible enzymes, including glucose oxidase (col. 04:40-44), and electron mediators (col. 05:66 – col. 06:03), Yamamoto does not mention using a Ru complex as electron mediator.

Nagakawa discloses an electrochemical analytical instrument comprising an oxidoreductase, such as PQQGDH, αGDH or CyGDH and a Ru complex as electron mediator. See the abstract and col. 03:44 – col. 04:56. In light of Nagakawa, using αGDH or CyGDH as oxidoreductase, or a Ru complex as an electron mediator in the analytical instrument of Yamamoto is just optimizing the reagent for the target analytes.

International Search Report for International Application No. PCT/JP2005/000153

("Search Report")

18. In the Search Report WO 2003/008956 A is cited as an "X" reference against claims 1, 8-10, 20, 23, 24, 33, and 35; and as a "Y" reference against claims 6, 7, 11, 21, 22, 23, and 34. No particular figures of or passages in WO 2003/008956 A are cited in the Search Report for meeting the limitations of these claims. So I can only guess what was intended. Claims 25-35 are non-elected in the instant application.

US 2004/0173458 A1 is an English language equivalent of WO 2003/008956 A.

Claim 1 requires "... at least part of the reagent portion is positioned adjacent to the introduction port." The only apparent disclosure for this limitation in US 2004/0173458 A1 appears to be Figures 8 and 10A, which are not drawn to scale. If this is so then Yamamoto and Nakaminami, which have been applied in rejections above, are closer prior art and so WO 2003/008956 A will not be applied in rejections.

19. In the Search Report JP 2002-333420 A is cited as an "X" reference against claims 1, 7, 8, 10, 11, 24, and 33; and as a "Y" reference against claims 6, 9, 20-23, 34, and 35. No particular figures of or passages in JP 2002-333420 A are cited in the Search Report for meeting the limitations of these claims. So I can only guess what was intended. Claims 25-35 are non-elected in the instant application.
US 6821410 B2 is an English language equivalent of JP 2002-333420 A. Claim 1 requires "… at least part of the reagent portion is positioned adjacent to the introduction port." The only apparent disclosure for this limitation in US 6821410 B2 appears to be Figures 6 and 8, which are not drawn to scale. If this is so then Yamamoto and Nakaminami, which have been applied in rejections above, are closer prior art and so JP 2002-333420 A in rejections.

20. In the Search Report WO 2003/057905 A is cited as an "Y" reference against claims 6, 21, 22, and 34, apparently as a secondary reference to WO 2003/008956 A. No particular figures of or passages in WO 2003/057905 A are cited in the Search Report for meeting the limitations of these claims. So I can only guess what was intended. Claims 25-35 are non-elected in the instant application. US 2004/0142406 A1 is an English language equivalent of WO 2003/057905 A. As noted above, in regard to claim 1, WO 2003/008956 A does not disclose more than Yamamoto and Nakaminami already do. Also, WO 2003/008956 A is deiced to an electrochemical sensor and WO

2003/057905 A is directed to an optical sensor. It is not clear how they are analogous art with regard to claims 6, 21, 22, and 34.

21. In the Search Report WO 2004/092725 A is cited as an "P,X" reference against claims 1, 6, 10, 11, 20-24, and 33-35. No particular figures of or passages in WO 2004/092725 A are cited in the Search Report for meeting the limitations of these claims. So I can only guess what was intended. Claims 25-35 are non-elected in the instant application. US 2007/0053790 A1 is an English language equivalent of WO 2004/092725 A. Claim 1 requires "... at least part of the reagent portion is positioned adjacent to the introduction port." The only apparent disclosure for this limitation in US 6821410 B2 appears to be Figures 1, 3, 4A, 4B, 11, 13, 14A, 14B, 15A, 15B, 16A, 16B, 17A, and 17B, which are not drawn to scale. However, in all of these figures the reagent portions are located in the middle of the flow path, not adjacent to an introduction port as claimed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795
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